

FOOD AND DRUG ADMINISTRATION (FDA)
Center for Drug Evaluation and Research (CDER)

Arthritis Advisory Committee (AAC) Meeting

FDA White Oak Campus, Building 31 Conference Center, the Great Room (Rm. 1503)
10903 New Hampshire Avenue, Silver Spring, Maryland
July 12, 2016

AGENDA

The committee will discuss biologics license application (BLA) 761024, for ABP 501, a proposed biosimilar to AbbVie Inc.'s HUMIRA (adalimumab), submitted by Amgen, Inc. The proposed indications (uses) for this product are: (1) Reducing signs and symptoms, inducing major clinical response, inhibiting the progression of structural damage, and improving physical function in adult patients with moderately to severely active rheumatoid arthritis (alone or in combination with methotrexate or other non-biologic disease-modifying anti-rheumatic drugs (DMARDs)); (2) reducing signs and symptoms of moderately to severely active polyarticular juvenile idiopathic arthritis in patients 4 years of age and older (alone or in combination with methotrexate); (3) reducing signs and symptoms, inhibiting the progression of structural damage, and improving physical function in adult patients with active psoriatic arthritis (alone or in combination with non-biologic DMARDs); (4) reducing signs and symptoms in adult patients with active ankylosing spondylitis; (5) reducing signs and symptoms and inducing and maintaining clinical remission in adult patients with moderately to severely active Crohn's disease who have had an inadequate response to conventional therapy (ABP 501 would be indicated for reducing signs and symptoms and inducing clinical remission in these patients if they have also lost response to or are intolerant to infliximab); (6) inducing and sustaining clinical remission in adult patients with moderately to severely active ulcerative colitis who have had an inadequate response to immunosuppressants such as corticosteroids, azathioprine or 6-mercaptopurine (6-MP) (the effectiveness of ABP-501 would not be established in patients who have lost response to or were intolerant to TNF blockers); and (7) treatment of adult patients with moderate to severe chronic plaque psoriasis who are candidates for systemic therapy or phototherapy, and when other systemic therapies are medically less appropriate (only to be administered to patients who will be closely monitored and have regular follow-up visits with a physician).

7:30 a.m.	Call to Order and Introduction of Committee	Daniel Solomon, MD, MPH Acting Chairperson, AAC
7:35 a.m.	Conflict of Interest Statement	Moon Hee Choi, PharmD Acting Designated Federal Officer, AAC
7:40 a.m.	FDA Opening Remarks	Janet Woodcock, MD Director CDER, FDA
7:50 a.m.	Overview of the Regulatory Pathway and FDA's Guidance for the Development and Approval of Biosimilar Products in the US	Leah Christl, PhD Associate Director, Therapeutic Biologics Therapeutic Biologics and Biosimilars Staff Office of New Drugs (OND), CDER, FDA
8:20 a.m.	Clarifying Questions to the FDA	
8:25 a.m.	FDA Introductory Remarks	Nikolay P. Nikolov, MD Clinical Team Leader Division of Pulmonary, Allergy & Rheumatology Products (DPARP) Office of Drug Evaluation II (ODE-II) OND, CDER, FDA

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AGENDA (cont.)

8:30 a.m.	APPLICANT PRESENTATIONS	Amgen, Inc.
	Introduction	Richard Markus, MD, PhD Vice President, Global Biosimilars Development Amgen, Inc.
	Analytical and Nonclinical Similarity to Adalimumab	Simon Hotchin Executive Director, Global Biosimilars Regulatory Affairs Amgen, Inc.
	ABP 501 Clinical Similarity	Richard Markus, MD, PhD
	Conclusions	Steven Galson, MD, MPH Senior Vice President, Global Regulatory Affairs & Safety Amgen, Inc.
10:00 a.m.	Clarifying Questions to Applicant	
10:15 a.m.	BREAK	
10:30 a.m.	FDA PRESENTATIONS	
	Product Quality Review	Joel Welch, PhD Product Quality Team Leader Division of Biotechnology Research and Review II Office of Biotechnology Products Office of Pharmaceutical Quality, CDER, FDA
	ABP 501 Statistical Equivalence Testing for Bioactivity	Meiyu Shen, PhD Lead Mathematical Statistician Division of Biometrics VI Office of Biostatistics (OB) Office of Translational Sciences (OTS), CDER, FDA
	Clinical Pharmacology Review	Jianmeng Chen, MD, PhD Clinical Pharmacology Reviewer Division of Clinical Pharmacology II Office of Clinical Pharmacology, OTS, CDER, FDA
	Clinical Efficacy Review	Yongman Kim, PhD Mathematical Statistician Division of Biometrics II, OB, OTS, CDER, FDA Kathleen Fritsch, PhD Mathematical Statistician Division of Biometrics III, OB, OTS, CDER, FDA

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AGENDA (cont.)

FDA PRESENTATIONS (CONT.)

Safety and Immunogenicity Review

Keith M. Hull, MD, PhD

Medical Officer

DPARP, ODE-II, OND, CDER, FDA

Considerations for Extrapolation and
Summary

Nikolay P. Nikolov, MD

12:00 p.m. Clarifying Questions to FDA

12:15 a.m. **LUNCH**

1:15 p.m. **OPEN PUBLIC HEARING**

2:45 p.m. Charge to the Committee

Nikolay P. Nikolov, MD

3:00 p.m. Questions to the Committee/Committee Discussion

3:30 p.m. **BREAK**

3:45 p.m. Questions to the Committee/Committee Discussion

5:00 p.m. **ADJOURNMENT**